

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

J&J Docket No. **DEP5205USNP**

MMB Docket No. **1671-0293**

Confirmation No.: **8391**

Application of: **Dietz et al.**

Group Art Unit: **3733**

Serial No. **10/814,953**

Examiner: **Pedro Philogene**

Filed: **March 31, 2004**

For: **Telemetric Tibial Tray**

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APPEAL BRIEF

Sir:

This is an appeal under 37 CFR § 41.31 to the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office from the rejection of the claims 1-2 and 8-18 of the above-identified patent application. These claims were indicated as rejected in an Office Action dated January 16, 2008. The \$510.00 fee required under 37 CFR § 41.20(b) (2) is submitted herewith. Also, please provide any extensions of time that may be necessary and charge any fees that may be due to Account No. 13-0014, but not to include any payment of issue fees.

(1) REAL PARTY IN INTEREST

DePuy Products, Inc. of Warsaw, Indiana is the assignee of this patent application, and the real party in interest.

(2) RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences related to this patent application (serial no. 10/814,953).

(3) STATUS OF CLAIMS

Claims 1-2 and 8-18 are pending in the application.

Claims 3-7 have been canceled.

Claims 1-2 and 8-18 are rejected.

Claims 1-2 and 8-18 are being appealed, and are shown in the Appendix attached to this Appeal Brief.

(4) STATUS OF AMENDMENTS

Appellants have filed no amendments after receipt of the January 16, 2008, Office Action (the "Office Action").

(5) SUMMARY OF CLAIMED SUBJECT MATTER

The present invention relates to a tibial tray for an implanted knee prosthesis with transducers to measure strain on the tibial tray. (See, e.g., Appellants' specification at

Abstract). In accordance with one embodiment, an upper plate 79 is attached to a lower plate 81 through support posts 86 projecting from load diaphragms 88. (See, e.g., Appellants' specification at page 11, lines 1-13, and FIGS. 4 and 5).

The support posts 86 have a circular cross-section and a diameter of about 5.0 mm that is about 1/3 the diameter of the corresponding one of said plurality of cavities (see, e.g., Appellants' specification at page 11, lines 18-25). The lower plate 81 further defines wiring channels 85 communicating between the transducer cavities 83 and a central cavity 84 housing the circuit board for the telemetric tray (see, e.g., Appellants' specification at page 14, lines 5-17 and FIG. 4). The wiring channels 85 are arranged at a 45 degree angle relative to the sagittal plane of the knee joint in order to reduce the effects of the wiring channel 85 intersection on the strain sensitivity of the tray. (See, e.g., Appellants' specification at page 14, lines 5-18 and FIG. 4). Each transducer cavity 83 includes a radial strain gage array with four pairs of radially aligned strain gages 90, 91, each pair aligned at a 45 degree angle relative to the sagittal plane of the knee joint. (See, e.g., Appellants' specification at page 13, lines 17-26 and FIG. 4). Each pair of strain gages includes an inner gage 90 positioned at the point of maximum positive micro-strain across the diaphragm when loaded (see, e.g., Appellants' specification at page 12, lines 29-30 and FIG. 4), and an outer gage 91 positioned at the point of maximum negative micro-strain, to thereby increase the differential strain measured by the gages and increase the strain sensitivity of the tibial tray. (See, e.g., Appellants' specification at page 13, lines 3-10).

The additional information required by the United States Patent Office is as follows.

Claim 1

Claim 1 is an independent claim. Claim 1 recites:

In a telemetric knee prosthesis adapted to measure forces transmitted across the knee joint, the knee prosthesis having a femoral component, a tibial bearing member in articulating contact with the femoral component, a tibia engaging member and a tibial tray engaged to the tibial bearing member and the tibia engaging member, the tibial tray comprising:

an upper plate having a portion configured for engaging the tibial bearing member (see, e.g., Appellants' specification at page 11, lines 8-9 and FIG. 1);

a lower plate having a portion configured for engaging the tibia engaging member (see, e.g., Appellants' specification at page 11, lines 4-5 and FIG. 1), said lower plate spaced apart from said upper plate and defining a plurality of cavities opening away from said upper plate (see, e.g., Appellants' specification at page 11, lines 10-11 and FIG. 4), each of said cavities including a diaphragm adapted to flex when subjected to a load normal to the diaphragm (see, e.g., Appellants' specification at page 11, lines 10-15 and FIG. 4);

a plurality of support posts, each connected between said upper plate and said diaphragm of a corresponding one of said plurality of cavities (see, e.g., Appellants' specification at page 11, lines 10-14 and FIG. 4), wherein said support posts are circular in cross-section and have a diameter that is about 1/3 the diameter of the corresponding one of said plurality of cavities (see, e.g. Appellants' specification at page 9, lines 18-25);
and

a force sensing element disposed within each of said plurality of cavities and operable to produce an output signal in response to flexing of said diaphragm (see, e.g. Appellants' specification at page 12, lines 11-13).

Claim 8

Claim 8 is an independent claim. Claim 8 recites:

In a telemetric knee prosthesis adapted to measure forces transmitted across the knee joint, the knee prosthesis having a femoral component, a tibial bearing member in articulating contact with the femoral component, a tibia engaging member and a tibial tray engaged to the tibial bearing member and the tibia engaging member, the tibial tray comprising:

an upper plate having a portion configured for engaging the tibial bearing member (see, e.g., Appellants' specification at page 11, lines 8-9 and FIG. 1);

a lower plate having a portion configured for engaging the tibia engaging member (see, e.g., Appellants' specification at page 11, lines 4-5 and FIG. 1), said lower plate spaced apart from said upper plate and defining a plurality of cylindrical cavities opening away from said upper plate (see, e.g., Appellants' specification at page 11, lines 10-11 and FIG. 4), each of said plurality of cylindrical cavities including a circular diaphragm adapted to flex when subjected to a load normal to the diaphragm and an outer wall (see, e.g., Appellants' specification at page 11, lines 10-15 and FIG. 4);

a plurality of support posts, each connected between said upper plate and said diaphragm of a corresponding one of said plurality of cylindrical cavities (see, e.g., Appellants' specification at page 11, lines 10-14 and FIG. 4); and

a force sensing element disposed within each of said plurality of cavities and operable to produce an output signal in response to flexing of said diaphragm, (see, e.g. Appellants' specification at page 12, lines 11-13) said force sensing element including four pairs of radially aligned strain gages (see, e.g. Appellants' specification at page 13, lines 3-16 and FIG. 4), the strain gages of each pair arranged to measure differential strain in a radial direction and includes an inner gage mounted on said diaphragm adjacent the center of said circular diaphragm (see, e.g. Appellants' specification at page 12, lines 25-30 and FIG. 4) and an outer gage mounted on said diaphragm immediately adjacent said outer wall of said cylindrical cavity (see, e.g. Appellants' specification at page 13, lines 3-17), wherein said circular diaphragm exhibits a micro-strain behavior under load that produces a maximum magnitude at a radial location from the center of said circular diaphragm (see, e.g. Appellants' specification at page 12, lines 25-30 and FIG. 6), and further wherein said inner gage is positioned to span said maximum magnitude radial location (see, e.g. Appellants' specification at page 12, lines 25-30 and FIG. 6).

Claim 9

Claim 9 is an independent claim. Claim 9 recites:

In a telemetric knee prosthesis adapted to measure forces transmitted across the knee joint, the knee prosthesis having a femoral component, a tibial bearing member in articulating contact with the femoral component, a tibia engaging member and a tibial tray engaged to the tibial bearing member and the tibia engaging member, the tibial tray comprising:

an upper plate having a portion configured for engaging the tibial bearing member(sec, e.g., Appellants' specification at page 11, lines 8-9 and FIG. 1);

a lower plate having a portion configured for engaging the tibia engaging member(sec, e.g., Appellants' specification at page 11, lines 4-5 and FIG. 1), said lower plate spaced apart from said upper plate and defining a plurality of cylindrical cavities opening away from said upper plate (sec, e.g., Appellants' specification at page 11, lines 10-11 and FIG. 4), each of said plurality of cylindrical cavities including a circular diaphragm adapted to flex when subjected to a load normal to the diaphragm and an outer wall (sec, e.g., Appellants' specification at page 11, lines 10-15 and FIG. 4);

a plurality of support posts, each connected between said upper plate and said diaphragm of a corresponding one of said plurality of cylindrical cavities (sec, e.g., Appellants' specification at page 11, lines 10-14 and FIG. 4); and

a force sensing element disposed within each of said plurality of cavities and operable to produce an output signal in response to flexing of said diaphragm (sec, e.g. Appellants' specification at page 12, lines 11-13), said force sensing element including four pairs of radially aligned strain gages (sec, e.g. Appellants' specification at page 13, lines 3-16 and FIG. 4), the strain gages of each pair arranged to measure differential strain in a radial direction and includes an inner gage mounted on said diaphragm adjacent the center of said circular diaphragm (sec, e.g. Appellants' specification at page 12, lines 25-30 and FIG. 4) and an outer gage mounted on said diaphragm immediately adjacent said outer wall of said cylindrical cavity, (sec, e.g. Appellants' specification at page 13, lines 3-17) wherein said circular diaphragm exhibits a micro-strain behavior under load that produces a zero-crossing point between the center of said circular diaphragm and said

outer wall of said cylindrical cavity (see, e.g. Appellants' specification at page 13, lines 3-16), and further wherein said outer gage is positioned between said zero-crossing point and said outer wall (see, e.g. Appellants' specification at page 13, lines 3-30, and FIGs. 4 and 6).

Claim 12

Claim 12 is an independent claim. Claim 12 recites:

In a telemetric knee prosthesis adapted to measure forces transmitted across the knee joint, the knee prosthesis having a femoral component, a tibial bearing member in articulating contact with the femoral component, a tibia engaging member and a tibial tray engaged to the tibial bearing member and the tibia engaging member, the tibial tray comprising:

an upper plate having a portion configured for engaging the tibial bearing member(see, e.g., Appellants' specification at page 11, lines 8-9 and FIG. 1);

a lower plate having a portion configured for engaging the tibia engaging member(see, e.g., Appellants' specification at page 11, lines 4-5 and FIG. 1), said lower plate spaced apart from said upper plate and defining a plurality of cavities opening away from said upper plate (see, e.g., Appellants' specification at page 11, lines 10-11 and FIG. 4), each of said plurality of cavities including a diaphragm adapted to flex when subjected to a load normal to the diaphragm (see, e.g., Appellants' specification at page 11, lines 10-15 and FIG. 4), said lower plate further defining a central cavity disposed between said plurality of cavities and a plurality of wiring channels (see, e.g. Appellants' specification at page 14, lines 5-17 and FIG. 4), each communicating between a

corresponding one of said plurality of cavities and said central cavity (see, e.g. Appellants' specification at page 13, lines 27-30, and page 14, lines 1-17);

a plurality of support posts, each connected between said upper plate and said diaphragm of a corresponding one of said plurality of cavities (see, e.g., Appellants' specification at page 11, lines 10-14 and FIG. 4);

a force sensing element disposed within each of said plurality of cavities and operable to produce an output signal in response to flexing of said diaphragm said force sensing element including four pairs of radially aligned strain gages (see, e.g. Appellants' specification at page 13, lines 3-16 and FIG. 4) the strain gages of each pair arranged to measure differential strain in a radial direction (see, e.g. Appellants' specification at page 12, lines 1-13);

a circuit element disposed in said central cavity for processing said output signal from said force sensing element in each of said plurality of cavities (see, e.g. Appellants' specification at page 14, lines 7-8); and

wiring electrically connecting each force sensing element in said plurality of cavities to said circuit element to transmit said output signal, said wiring disposed in a corresponding one of said plurality of wiring channels (see, e.g. Appellants' specification at page 14, lines 1-27),

wherein said lower plate defines a plane perpendicular to the sagittal plane of the knee joint when the knee prosthesis is implanted therein (see, e.g. Appellants' specification at page 14, lines 1-2 and FIG. 4),

wherein each of said four pairs of strain gages is aligned in a one of two radial planes that are at about 45 degrees relative to said sagittal plane (see, e.g. Appellants' specification at page 13, lines 21-26), and

wherein none of said four pairs of radially aligned strain gages is aligned with said wiring channel communicating with said corresponding one of said plurality of cavities (see, e.g. Appellants' specification at page 14, lines 18-25).

Claim 14

Claim 14 is an independent claim. Claim 14 recites:

A telemetric knee prosthesis comprising:

an upper tibial tray plate having a portion configured for coupling with a tibial bearing member(see, e.g., Appellants' specification at page 11, lines 8-9 and FIG. 1);

a lower tibial tray plate spaced apart from the upper tibial tray plate and defining a plurality of cavities opening away from the upper tibial tray plate (see, e.g., Appellants' specification at page 11, lines 4-5 and FIG. 1), each of the plurality of cavities including an outer wall and a diaphragm adapted to flex when subjected to a load on the diaphragm (see, e.g., Appellants' specification at page 11, lines 10-15 and FIG. 4);

a plurality of support posts, each of the plurality of support posts extending between the upper tibial tray plate and the diaphragm of a corresponding one of the plurality of cavities (see, e.g., Appellants' specification at page 11, lines 10-14 and FIG. 4); and

a plurality of force sensing elements, each of the plurality of force sensing elements disposed within one of the plurality of cavities and operable to produce an

output signal in response to flexing of the diaphragm in the respective one of the plurality of cavities (see, e.g. Appellants' specification at page 12, lines 11-13), each of the plurality of force sensing elements including an inner gage positioned such that at least a portion of the inner gauge is mounted at a location on one side of the diaphragm directly opposite to where a portion of the corresponding one of the plurality of support posts contacts the other side of the diaphragm (see, e.g. Appellants' specification at page 11, lines 29-31 and FIGs. 4 and 6).

(6) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1-2 and 8-18 stand rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 7,179,295 to Kovacevic (hereinafter "Kovacevic") in view of U.S. Patent No. 5,365,799 to Okada (hereinafter "Okada").

(7) ARGUMENT

Claims 1-2 and 8-18 Are Not Obvious

Claims 1-2 and 8-18 stand rejected under 35 U.S.C. §103(a) as being obvious over Kovacevic in view of Okada. (Office Action at page 2). As discussed below, these rejections should be overturned.

Discussion re: Patentability of Claim 1

1. Claim 1

Claim 1 recites the following:

In a telemetric knee prosthesis adapted to measure forces transmitted across the knee joint, the knee prosthesis having a femoral component, a tibial bearing member in articulating contact with the femoral component, a tibia engaging member and a tibial tray engaged to the tibial bearing member and the tibia engaging member, the tibial tray comprising:

an upper plate having a portion configured for engaging the tibial bearing member;

a lower plate having a portion configured for engaging the tibia engaging member, said lower plate spaced apart from said upper plate and defining a plurality of cavities opening away from said upper plate, each of said cavities including a diaphragm adapted to flex when subjected to a load normal to the diaphragm;

a plurality of support posts, each connected between said upper plate and said diaphragm of a corresponding one of said plurality of cavities, wherein said support posts are circular in cross-section and have a diameter that is about 1/3 the diameter of the corresponding one of said plurality of cavities; and

a force sensing element disposed within each of said plurality of cavities and operable to produce an output signal in response to flexing of said diaphragm.

Accordingly, claim 1 recites a telemetric knee prosthesis that has support posts that have a diameter that is about 1/3 the diameter of the corresponding one of the plurality of cavities.

2. The Basis for the Modification Has Not Been Articulated

The Examiner rejected claim 1 based upon a combination of Kovacevic and Okada. (Office Action at page 2). The Examiner has failed to clearly articulate a basis for the proposed modification.

Specifically, the Examiner reasons that the proposed modification would be “to detect components in respective axial directions of an applied force on the basis of a pattern of charges produced.” (Office Action at page 4). The Examiner thus appears to rely upon MPEP 2144 which notes that “[t]he strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination.” Citing, In re Sernaker, 702 F.2d 989, 994-95, 217 USPQ 1, 5-6 (Fed. Cir.

1983). Kovacevic, however, *already provides* the result proposed by the Examiner. As seen in FIG. 30 of Kovacevic, four sensors 460 are located in a cross pattern. Thus, the sensors 460 of Kovacevic “allow forces to be measured throughout plate 402.” (Kovacevic at column 8, lines 31-32).

Therefore, while a reason to combine references may be found in an advantage arising from the combination, there can be no advantage from the proposed combination when the alleged advantage is *already present* in the system which the Examiner proposes to modify. Accordingly, the Examiner has failed to articulate a legally cognizable reason for the combination of Kovacevic and Okada. Consequently, the Examiner has failed to establish a *prima facie* case of obviousness and the Board of Appeals is respectfully requested to reverse this rejection of claim 1.

3. The Claim Elements Cannot Be Ignored

The Examiner admits that “the above combination of references did not teach of support posts having a diameter that is about 1/3 the diameter of the corresponding one of the plurality of cavities.” (Office Action at page 3). The Examiner then asserts that “applicant fails to establish the criticality of that dimension” and that “any such dimensions could have been used and the device would have equally (sic) as well.” (Office Action at page 3). The Examiner has failed to consider each element in the claim.

The Examiner did not rely upon an allegation of Official Notice that the limitation of “about 1/3 the diameter” was non-critical. Rather, the Examiner merely chose to disregard the limitation alleging that the Applicants failed to establish criticality of the

limitation. Disregarding a claim limitation is contrary to established procedure and legal precedent. Specifically, MPEP 2143.03 notes that “[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art.” Quoting, *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). Therefore, the limitation of “about 1/3 the diameter” cannot simply be disregarded.

Accordingly, because claim 1 includes a limitation of a telemetric knee prosthesis that has support posts with a diameter that is about 1/3 the diameter of the corresponding one of a plurality of cavities, and because the Examiner has failed to identify any teaching, disclosure or suggestion in the prior art for a device with support posts having a diameter that is about 1/3 the diameter of the corresponding one of a plurality of cavities, a *prima facie* case of obviousness under 35 USC § 103 has not been established with regard to claim 1. Therefore, the Board of Appeals is respectfully requested to reverse the rejection of claim 1.

4. The Examiner has Disregarded the Specification

Moreover, the Examiner’s assertion that the limitation of “about 1/3 the diameter” was non-critical is contrary to the teaching of the present specification. For example, at page 6, lines 10-17, the Appellants’ specification states:

...the primary function of the implant is to serve as a prosthetic joint, and not simply as a data transmission device, the implant must be able to withstand joint loads without failure. Load is transmitted from the femur to the tibia through the large articulating surface areas of the condylar surfaces **16** and the bearing surfaces **28**. However, once the load reaches the tibial tray, such as the tibial tray **44**, the force is transmitted through four support posts **52** into the tibia. Therefore, it can be appreciated that the strength of these posts is critical to the strength of the implant.

Additionally, the benefits of one embodiment are detailed in the Appellants' specification which notes:

The cross-sectional area of these posts is about 20mm^2 , which is over three times larger than the cross-sectional area (6.25mm^2) of the prior devices. This significantly greater cross-sectional area means that the support posts **86** have greater load bearing capacity with a longer fatigue life than the prior devices. In a preferred embodiment of the invention, the diameter of the support posts is about $1/3$ the diameter of the transducer cavity.

(Appellants' specification at page 11, lines 19-25).

Therefore, the benefit provided by the recited limitation of the posts is well documented within the Appellants' specification. The Examiner has disregarded the teaching of the specification without providing any insight as to the basis for such disregard.

5. The Examiner has Failed to Identify a Source for the Allegations

Moreover, the Appellants' specification, as discussed above, identifies a unique environment in which the disclosed invention is used, an environment wherein the support posts are subjected to repeated cycling under load. A reasonable conclusion in consideration of the realities of such an environment is that the physical properties of the support posts will have an appreciable affect on the functionality of the device.

The Examiner's contention that "any such dimensions could have been used" (Office Action at page 3) is thus contrary to the expected influence of the physical properties of a support post on the functionality of the device. The Examiner, however, has failed to provide any basis for his position.

As set forth in the MPEP at 2143, "[t]he key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have

been obvious.” An allegation of a result that is contrary to expected phenomena, and contrary to the teaching of the present specification, made without any scientific support, cannot be a “clear articulation.” Therefore, the Board of Appeals is respectfully requested to reverse the rejection of claim 1.

6. The “Optimum Value” Argument is Misplaced

Finally, with reference to *In re Boesch*, the Examiner has opined that the implementation of a support post in the manner recited in claim 1 is merely an optimum value “of a result effective variable.” (Office Action at page 4). The Examiner’s reliance on *In re Boesch* is misplaced.

Specifically, *In re Boesch* dealt with a claim limitation which was *encompassed* by the prior art. *In re Boesch*, 205 USPQ 215,218 (CCPA 1980). Accordingly, the Court held that finding an optimum value *within the previously known range* was within the ordinary skill in the art. The Examiner, however, has failed to identify any teaching in the prior art that encompasses the limitation recited in claim 1.

Therefore, because *In re Boesch* was directed to optimizing a value within a previously disclosed range, and because the Examiner has failed to identify any previously existing range encompassing the limitation of support posts that have a diameter that is about 1/3 the diameter of the corresponding one of the plurality of cavities, the Examiner’s reliance on *In re Boesch* is misplaced. Accordingly, because there is no basis for the Examiner’s assertion regarding the “about 1/3 diameter” limitation, a *prima facie* case of obviousness under 35 USC § 103 has not been

established with regard to claim 1. Therefore, the Board of Appeals is respectfully requested to reverse the rejection of claim 1.

7. Conclusion

For some or all of the above reasons, claim 1 is not obvious in view of the prior art. Accordingly, the Board of Appeals is respectfully requested to reverse this rejection of claim 1.

Discussion re: Patentability of Claim 2

1. Claim 2

Claim 2 depends from claim 1, and adds the limitation “wherein said support posts each have a diameter of about 5.0 mm.”

2. The Discussion of Claim 1 Applies

Claim 2 thus includes the same elements discussed above with respect to claim 1. Claim 2 was rejected based upon the same prior art and the same proposed motivation discussed above with respect to claim 1. (Office Action at page 2). Accordingly, claim 2 is patentable over the prior art for at least the same reasons as those set forth above in connection with claim 1.

3. Prima Facie Case Has Not Been Properly Alleged

Moreover, to establish a *prima facie* case of obviousness, “there must be some articulated reasoning with some rational underpinning to support the legal conclusion of

obviousness.” MPEP 2142, quoting, *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). While the examiner has alleged that the use of a support post with a diameter of about 5 millimeters is obvious, the Examiner has failed to provide any citation of such a support post in the prior art or any rationale for providing such a support post. In fact, the Appellants have not been able to identify any discussion of the limitations of claim 2 in the Office Action.

Accordingly, because there is no basis for the Examiner’s assertion regarding any alleged obviousness of a support post with a diameter of about 5 millimeters, a *prima facie* case of obviousness under 35 USC § 103 has not been established with regard to claim 2. Therefore, the Board of Appeals is respectfully requested to reverse the rejection of claim 2.

4. Conclusion

Therefore, for any of the reasons set forth above, a *prima facie* case of obviousness has not been established with respect to the invention of claim 2 and the Board of Appeals is respectfully requested to reverse the rejection of claim 2.

Discussion re: Patentability of Claim 8

1. Claim 8

Claim 8 recites:

In a telemetric knee prosthesis adapted to measure forces transmitted across the knee joint, the knee prosthesis having a femoral component, a tibial bearing member in articulating contact with the femoral component, a tibia engaging member and a tibial tray engaged to the tibial bearing member and the tibia engaging member, the tibial tray comprising:

an upper plate having a portion configured for engaging the tibial bearing member;

a lower plate having a portion configured for engaging the tibia engaging member, said lower plate spaced apart from said upper plate and defining a plurality of cylindrical cavities opening away from said upper plate, each of said plurality of cylindrical cavities including a circular diaphragm adapted to flex when subjected to a load normal to the diaphragm and an outer wall;

a plurality of support posts, each connected between said upper plate and said diaphragm of a corresponding one of said plurality of cylindrical cavities; and

a force sensing element disposed within each of said plurality of cavities and operable to produce an output signal in response to flexing of said diaphragm, said force sensing element including four pairs of radially aligned strain gages, the strain gages of each pair arranged to measure differential strain in a radial direction and includes an inner gage mounted on said diaphragm adjacent the center of said circular diaphragm and an outer gage mounted on said diaphragm immediately adjacent said outer wall of said cylindrical cavity, wherein said circular diaphragm exhibits a micro-strain behavior under load that produces a maximum magnitude at a radial location from the center of said circular diaphragm, and further wherein said inner gage is positioned to span said maximum magnitude radial location.

Accordingly, claim 8 recites a knee prosthesis that includes four pairs of radially aligned strain gages each pair including an inner gage mounted on the diaphragm adjacent the center of the circular diaphragm at a location which spans a maximum magnitude radial location.

2. A Reason for the Modification Has Not Been Clearly Articulated

The Examiner rejected claim 8 based upon the same combination of Kovacevic and Okada discussed above with respect to claim 1. (Office Action at page 2). The Examiner further alleged the same motivation for the proposed combination as discussed above with respect to claim 1. (Office Action at page 4). Therefore, for the same reason discussed above with respect to claim 1, the Examiner has failed to clearly articulate a reason for modifying the device of Kovacevic with the device of Okada.

Consequently, the Examiner has failed to establish a *prima facie* case of obviousness and the Board of Appeals is respectfully requested to reverse this rejection of claim 8.

3. Prima Facie Case Has Not Been Properly Alleged

Moreover, the Examiner has alleged that Okada discloses an “inner gage” that is “positioned to span the maximum magnitude radial location.” (Office Action at page 4). The Examiner has failed to provide a basis for this assertion.

Specifically, the Examiner provides no insight as to where in Okada a gage is shown which spans a maximum magnitude radial location. The Examiner offers only a conclusory determination that Okada discloses this element.

To establish a *prima facie* case of obviousness, “there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” MPEP 2142, quoting, *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). Because the Examiner has not identified any support or provided any rationale for the assertion that Okada discloses an “inner gage” that is “positioned to span the maximum magnitude radial location,” a *prima facie* case of obviousness under 35 USC § 103 has not been established with regard to claim 8. Therefore, the Board of Appeals is respectfully requested to reverse the rejection of claim 8.

4. Conclusion

For some or all of the above reasons, claim 8 is not obvious in view of the prior art. Accordingly, the Board of Appeals is respectfully requested to reverse the rejection of claim 8.

Discussion re: Patentability of Claim 9

1. Claim 9

Claim 9 recites:

In a telemetric knee prosthesis adapted to measure forces transmitted across the knee joint, the knee prosthesis having a femoral component, a tibial bearing member in articulating contact with the femoral component, a tibia engaging member and a tibial tray engaged to the tibial bearing member and the tibia engaging member, the tibial tray comprising:

an upper plate having a portion configured for engaging the tibial bearing member;

a lower plate having a portion configured for engaging the tibia engaging member, said lower plate spaced apart from said upper plate and defining a plurality of cylindrical cavities opening away from said upper plate, each of said plurality of cylindrical cavities including a circular diaphragm adapted to flex when subjected to a load normal to the diaphragm and an outer wall;

a plurality of support posts, each connected between said upper plate and said diaphragm of a corresponding one of said plurality of cylindrical cavities; and

a force sensing element disposed within each of said plurality of cavities and operable to produce an output signal in response to flexing of said diaphragm, said force sensing element including four pairs of radially aligned strain gages, the strain gages of each pair arranged to measure differential strain in a radial direction and includes an inner gage mounted on said diaphragm adjacent the center of said circular diaphragm and an outer gage mounted on said diaphragm immediately adjacent said outer wall of said cylindrical cavity, wherein said circular diaphragm exhibits a micro-strain behavior under load that produces a zero-crossing point between the center of said circular diaphragm and said outer wall of said cylindrical cavity, and further wherein said outer gage is positioned between said zero-crossing point and said outer wall.

Accordingly, claim 9 recites a knee prosthesis that includes four pairs of radially aligned strain gages each pair including an outer gage mounted on the diaphragm immediately adjacent the outer wall of the cylindrical cavity and radially outwardly of a zero-crossing point.

2. A Reason for the Modification Has Not Been Clearly Articulated

The Examiner rejected claim 9 based upon the same combination of Kovacevic and Okada discussed above with respect to claim 1. (Office Action at page 2). The Examiner further alleged the same motivation for the proposed combination as discussed above with respect to claim 1. (Office Action at page 4). Therefore, for the same reason

discussed above with respect to claim 1, the Examiner has failed to clearly articulate a reason for modifying the device of Kovacevic with the device of Okada.

Consequently, the Examiner has failed to establish a *prima facie* case of obviousness and the Board of Appeals is respectfully requested to reverse this rejection of claim 9.

3. Prima Facie Case Has Not Been Properly Alleged

Moreover, the Examiner has alleged that Okada discloses an “outer gage” that is “positioned between the zero crossing point and the outer wall.” (Office Action at page 4). The Examiner has failed to provide a valid basis for this assertion.

Specifically, the Examiner cites to FIGs. 18 and 19 along with column 14, lines 45-67 and column 15, lines 1-42 of the references for the element above.¹ (Office Action at page 4). The Examiner failed to identify what particular teaching led to the conclusion that the outer gages of Okada are positioned between the zero crossing point and the outer wall, and the Appellants have not found any such teaching. The only consideration regarding the positioning of the elements of Okada that the Appellants have discovered is that the area of the elements in FIG. 18 is smaller so as to fit more gages into the area (Okada at column 14, lines 51-55) and the orientations of the elements are selected to provide response along various axes (Okada at column 14, lines 54-57). Thus, the disclosure of Okada does not provide a factual basis for the Examiner’s conclusion.

¹ The Examiner states that the reference is “Kovacevic.” (Office Action at page 4). Based upon a review of FIGs. 18-19 of Okada and Kovacevic, and since Kovacevic only shows 12 columns, the Examiner apparently intended to reference Okada.

To establish a *prima facie* case of obviousness, “there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” MPEP 2142, quoting, *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). Because the Examiner has not identified any underpinning in the cited reference or any rationale for the assertion that Okada discloses an “outer gage” that is “positioned between the zero crossing point and the outer wall,” a *prima facie* case of obviousness under 35 USC § 103 has not been established with regard to claim 9. Therefore, the Board of Appeals is respectfully requested to reverse the rejection of claim 9.

4. Conclusion

For some or all of the above reasons, claim 9 is not obvious in view of the prior art. Accordingly, the Board of Appeals is respectfully requested to reverse the rejection of claim 9.

Discussion re: Patentability of Claim 10

1. Claim 10

Claim 10 recites:

The tibial tray of claim 9, wherein said circular diaphragm exhibits a micro-strain behavior under load that produces a negative maximum magnitude at a radial location between said zero-crossing point and said outer wall, and further wherein said outer gage is positioned to span said negative maximum magnitude radial location.

Accordingly, claim 10 depends from claim 9 and further recites that the outer gage is positioned to span a negative maximum magnitude radial location.

2. The Discussion of Claim 9 Applies

Claim 10 thus includes the same elements discussed above with respect to claim 9. Claim 10 was rejected based upon the same prior art and the same proposed motivation discussed above with respect to claim 9. (Office Action at page 2). Accordingly, claim 10 is patentable over the prior art for at least the same reasons as those set forth above in connection with claim 9.

3. Prima Facie Case Has Not Been Properly Alleged

Moreover, to establish a *prima facie* case of obviousness, “there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” MPEP 2142, quoting, *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). While the examiner has apparently alleged that an outer gage positioned to span a negative maximum magnitude radial location is obvious, the Examiner has failed to provide any citation of such placement of an outer gage in the prior art or any rationale for providing an outer gage in such a placement for use in a tibial tray. In fact, the Appellants have not been able to identify any discussion of the limitations of claim 10 in the Office Action.

Accordingly, because there is no basis for the Examiner’s assertion regarding the obviousness of an outer gage positioned to span a negative maximum magnitude radial location, a *prima facie* case of obviousness under 35 USC § 103 has not been established with regard to claim 10. Therefore, the Board of Appeals is respectfully requested to reverse the rejection of claim 10.

4. Conclusion

Therefore, for any of the reasons set forth above, a *prima facie* case of obviousness has not been established with respect to the invention of claim 10 and the Board of Appeals is respectfully requested to reverse the rejection of claim 10.

Discussion re: Patentability of Claim 11

1. Claim 11

Claim 11 recites:

The tibial tray of claim 9, wherein said circular diaphragm further exhibits a micro-strain behavior under load that produces a positive maximum magnitude at a radial location from the center of said circular diaphragm, and further wherein said inner gage is positioned to span said positive maximum magnitude radial location.

Accordingly, claim 11 depends from claim 9 and further recites that the inner gage is positioned to span a positive maximum magnitude radial location.

2. The Discussion of Claim 9 Applies

Claim 11 thus includes the same elements discussed above with respect to claim 9. Claim 11 was rejected based upon the same prior art and the same proposed motivation discussed above with respect to claim 9. (Office Action at page 2). Accordingly, claim 11 is patentable over the prior art for at least the same reasons as those set forth above in connection with claim 9.

3. Prima Facie Case Has Not Been Properly Alleged

Moreover, the limitation of an inner gage positioned to span a positive maximum magnitude radial location is the same limitation that was discussed above with respect to

claim 8. Therefore, for the same reason set forth with respect to the inner gage limitation of claim 8, a *prima facie* case of obviousness under 35 USC § 103 has not been established with regard to claim 11. Therefore, the Board of Appeals is respectfully requested to reverse the rejection of claim 11.

4. Conclusion

Therefore, for any of the reasons set forth above, a *prima facie* case of obviousness has not been established with respect to the invention of claim 11 and the Board of Appeals is respectfully requested to reverse the rejection of claim 11.

Discussion re: Patentability of Claim 12

1. Claim 12

Claim 12 recites:

In a telemetric knee prosthesis adapted to measure forces transmitted across the knee joint, the knee prosthesis having a femoral component, a tibial bearing member in articulating contact with the femoral component, a tibia engaging member and a tibial tray engaged to the tibial bearing member and the tibia engaging member, the tibial tray comprising:

an upper plate having a portion configured for engaging the tibial bearing member;

a lower plate having a portion configured for engaging the tibia engaging member, said lower plate spaced apart from said upper plate and defining a plurality of cavities opening away from said upper plate, each of said plurality of cavities including a diaphragm adapted to flex when subjected to a load normal to the diaphragm, said lower plate further defining a central cavity disposed between said plurality of cavities and a plurality of wiring channels, each communicating between a corresponding one of said plurality of cavities and said central cavity;

a plurality of support posts, each connected between said upper plate and said diaphragm of a corresponding one of said plurality of cavities;

a force sensing element disposed within each of said plurality of cavities and operable to produce an output signal in response to flexing of said diaphragm said force sensing element including four pairs of radially aligned strain gages, the strain gages of each pair arranged to measure differential strain in a radial direction;

a circuit element disposed in said central cavity for processing said output signal from said force sensing element in each of said plurality of cavities; and

wiring electrically connecting each force sensing element in said plurality of cavities to said circuit element to transmit said output signal, said wiring disposed in a corresponding one of said plurality of wiring channels,
 wherein said lower plate defines a plane perpendicular to the sagittal plane of the knee joint when the knee prosthesis is implanted therein,
 wherein each of said four pairs of strain gages is aligned in a one of two radial planes that are at about 45 degrees relative to said sagittal plane, and
 wherein none of said four pairs of radially aligned strain gages is aligned with said wiring channel communicating with said corresponding one of said plurality of cavities.

Accordingly, claim 12 recites a knee prosthesis that includes four pairs of radially aligned strain gages which are aligned in a one of two radial planes that are at about 45 degrees relative to a sagittal plane.

2. A Reason for the Modification Has Not Been Clearly Articulated

The Examiner rejected claim 12 based upon the same combination of Kovacevic and Okada discussed above with respect to claim 1. (Office Action at page 2). The Examiner further alleged the same motivation for the proposed combination as discussed above with respect to claim 1. (Office Action at page 4). Therefore, for the same reason discussed above with respect to claim 1, the Examiner has failed to clearly articulate a reason for modifying the device of Kovacevic with the device of Okada.

Consequently, the Examiner has failed to establish a *prima facie* case of obviousness and the Board of Appeals is respectfully requested to reverse this rejection of claim 12.

3. The Reference Has Been Mischaracterized

Moreover, the Examiner has alleged that Kovacevic discloses four gages aligned at 45 degrees relative to a sagittal plane. (Office Action at page 4). The Examiner has mischaracterized the reference.

Specifically, the Examiner cites to FIG. 18 of Kovacevic for this limitation.

(Office Action at page 4). FIG. 18 of Kovacevic is set forth below.

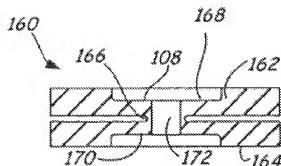


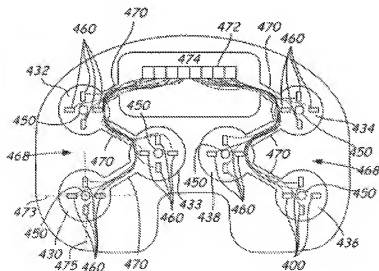
FIG. 18

FIG. 18 does not disclose *any* sensors. Rather, FIG. 18 only discloses a “shock absorber.”

(Kovacevic at column 6, lines 46-53).

Likewise, FIG. 18 of Okada does not support the Examiner’s allegation. The device in FIG. 18 of Okada is not depicted as attached to any component.

The only disclosure that the Appellants have discovered that is relevant to the “45 degree” element is FIG. 32 of Kovacevic which is set forth below.



As is evident from FIG. 32, the elements 460 are positioned in a sagittal plane (i.e., parallel with reference line 473) or perpendicular to a sagittal plane. An element positioned parallel to or perpendicular to a sagittal plane is not the same as an element positioned at a 45 degree angle relative to a sagittal plane.

To establish a *prima facie* case of obviousness, “there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” MPEP 2142, quoting, *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). Because the Examiner has not identified any underpinning in the cited reference or any rationale for the assertion that the prior art discloses four gages aligned at 45 degrees relative to a sagittal plane, a *prima facie* case of obviousness under 35 USC § 103 has not been established with regard to claim 12. Therefore, the Board of Appeals is respectfully requested to reverse the rejection of claim 12.

4. Conclusion

For some or all of the above reasons, claim 12 is not obvious in view of the prior art. Accordingly, the Board of Appeals is respectfully requested to reverse the rejection of claim 12.

Discussion re: Patentability of Claim 13

Claim 13 depends from claim 12 and includes all of the limitations of claim 12 plus additional limitations. Claim 13 was rejected based upon the same prior art and the same proposed motivation discussed above with respect to claim 12. (Office Action at

page 2). Accordingly, claim 13 is patentable over the prior art for at least the same reasons as those set forth above in connection with claim 12.

Discussion re: Patentability of Claim 14

1. Claim 14

Claim 14 recites:

A telemetric knee prosthesis comprising:
 an upper tibial tray plate having a portion configured for coupling with a tibial bearing member;
 a lower tibial tray plate spaced apart from the upper tibial tray plate and defining a plurality of cavities opening away from the upper tibial tray plate, each of the plurality of cavities including an outer wall and a diaphragm adapted to flex when subjected to a load on the diaphragm;
 a plurality of support posts, each of the plurality of support posts extending between the upper tibial tray plate and the diaphragm of a corresponding one of the plurality of cavities; and
 a plurality of force sensing elements, each of the plurality of force sensing elements disposed within one of the plurality of cavities and operable to produce an output signal in response to flexing of the diaphragm in the respective one of the plurality of cavities, each of the plurality of force sensing elements including an inner gage positioned such that at least a portion of the inner gage is mounted at a location on one side of the diaphragm directly opposite to where a portion of the corresponding one of the plurality of support posts contacts the other side of the diaphragm.

Accordingly, claim 14 recites a knee prosthesis that includes four pairs of radially aligned strain gages with an inner gage positioned at a location on one side of the diaphragm directly opposite to where a portion of a support post contacts the other side of the diaphragm.

2. A Reason for the Modification Has Not Been Clearly Articulated

The Examiner rejected claim 14 based upon the same combination of Kovacevic and Okada discussed above with respect to claim 1. (Office Action at page 2). The Examiner further alleged the same motivation for the proposed combination as discussed above with respect to claim 1. (Office Action at page 4). Therefore, for the same reason

discussed above with respect to claim 1, the Examiner has failed to clearly articulate a reason for modifying the device of Kovacevic with the device of Okada.

Consequently, the Examiner has failed to establish a *prima facie* case of obviousness and the Board of Appeals is respectfully requested to reverse this rejection of claim 14.

3. The Reference Has Been Mischaracterized

Moreover, the Examiner has alleged that Okada discloses an inner gage positioned at a location on one side of the diaphragm directly opposite to where a portion of a support post contacts the other side of the diaphragm. (Office Action at page 5). The Examiner has failed to provide a valid basis for this assertion.

Specifically, the Examiner cites to column 15, lines 17-42 for the element above.² (Office Action at page 4). The Examiner failed to identify what particular teaching led to the conclusion that Okada discloses an inner gage positioned at a location on one side of the diaphragm directly opposite to where a portion of a support post contacts the other side of the diaphragm, and the Appellants have not found any such teaching. The portion of Okada identified by the Examiner merely discusses changing the location of the working body 50 from a central location on the diaphragm to the outer periphery of the diaphragm. FIG. 19, which is described by Okada at column 15, lines 17-42, is set forth below.

² The Examiner states that the reference is “Kovacevic.” (Office Action at page 4). Based upon a review of FIGs. 18-19 of Okada and Kovacevic, and since Kovacevic only shows 12 columns, the Examiner apparently intended to reference Okada.

FIG. 19

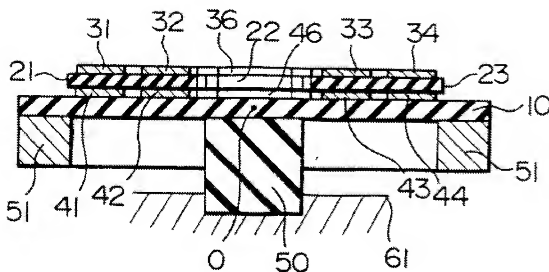


FIG. 19 clearly shows that neither of the elements 21 and 23 are positioned on the substrate 10 at a location directly opposite to the working body 50. Thus, the disclosure of Okada does not provide a factual basis for the Examiner's allegation.

To establish a *prima facie* case of obviousness, "there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." MPEP 2142, quoting, *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). Because the Examiner has not identified any underpinning in the cited reference or any rationale for the assertion that Okada discloses an inner gage positioned at a location on one side of the diaphragm directly opposite to where a portion of a support post contacts the other side of the diaphragm, a *prima facie* case of obviousness under 35 USC § 103 has not been established with regard to claim 14. Therefore, the Board of Appeals is respectfully requested to reverse the rejection of claim 14.

4. Conclusion

For some or all of the above reasons, claim 14 is not obvious in view of the prior art. Accordingly, the Board of Appeals is respectfully requested to reverse the rejection of claim 14.

Discussion re: Patentability of Claims 15 and 18

Claims 15 and 18 depend from claim 14 and include all of the limitations of claim 14 plus additional limitations. Claims 15 and 18 were rejected based upon the same prior art and the same proposed motivation discussed above with respect to claim 14. (Office Action at page 2). Accordingly, claims 15 and 18 are patentable over the prior art for at least the same reasons as those set forth above in connection with claim 14.

Discussion re: Patentability of Claim 16

1. Claim 16

Claim 16 recites:

The tibial tray of claim 14, wherein the diaphragm is a circular diaphragm which exhibits a micro-strain behavior under load that produces a maximum magnitude at a radial location from the center of the circular diaphragm, and further wherein the inner gage is positioned to span the maximum magnitude radial location

Accordingly, claim 16 depends from claim 14 and further recites that the inner gage is positioned to span a positive maximum magnitude radial location.

2. The Discussion of Claim 14 Applies

Claim 16 thus includes the same elements discussed above with respect to claim 14. Claim 16 was rejected based upon the same prior art and the same proposed motivation discussed above with respect to claim 14. (Office Action at page 2). Accordingly, claim 16 is patentable over the prior art for at least the same reasons as those set forth above in connection with claim 14.

3. Prima Facie Case Has Not Been Properly Alleged

Moreover, the limitation of an inner gage positioned to span a positive maximum magnitude radial location is the same limitation that was discussed above with respect to claim 8. Therefore, for the same reason set forth with respect to the inner gage limitation of claim 8, a *prima facie* case of obviousness under 35 USC § 103 has not been established with regard to claim 16. Therefore, the Board of Appeals is respectfully requested to reverse the rejection of claim 16.

4. Conclusion

Therefore, for any of the reasons set forth above, a *prima facie* case of obviousness has not been established with respect to the invention of claim 16 and the Board of Appeals is respectfully requested to reverse the rejection of claim 16.

Discussion re: Patentability of Claim 17

1. Claim 17

Claim 17 recites:

The tibial tray of claim 16, wherein:
 the circular diaphragm exhibits a micro-strain behavior under load that produces a zero-crossing point between the center of the circular diaphragm and the outer wall of the cylindrical cavity; and
 each of the plurality of force sensing elements further comprises an outer gage positioned between the zero-crossing point and the outer wall.

Accordingly, claim 17 depends from claim 14 and further recites that the outer gage is positioned between the zero-crossing point and the outer wall.

2. The Discussion of Claim 14 Applies

Claim 17 thus includes the same elements discussed above with respect to claim 14. Claim 17 was rejected based upon the same prior art and the same proposed motivation discussed above with respect to claim 14. (Office Action at page 2). Accordingly, claim 17 is patentable over the prior art for at least the same reasons as those set forth above in connection with claim 14.

3. Prima Facie Case Has Not Been Properly Alleged

Moreover, the limitation of an outer gage positioned between the zero-crossing point and the outer wall is the same limitation that was discussed above with respect to claim 9. Therefore, for the same reason set forth with respect to the outer gage limitation of claim 9, a *prima facie* case of obviousness under 35 USC § 103 has not been established with regard to claim 17. Therefore, the Board of Appeals is respectfully requested to reverse the rejection of claim 17.

4. Conclusion

Therefore, for any of the reasons set forth above, a *prima facie* case of obviousness has not been established with respect to the invention of claim 17 and the Board of Appeals is respectfully requested to reverse the rejection of claim 17.

CONCLUSION

Claims 1-2 and 8-18 are not obvious over Kovacevic in view of Okada. Accordingly, the Board of Appeals is respectfully requested to reverse the rejections of claims 1-2 and 8-18.

Respectfully submitted,

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(8) CLAIMS APPENDIX

Claim 1. In a telemetric knee prosthesis adapted to measure forces transmitted across the knee joint, the knee prosthesis having a femoral component, a tibial bearing member in articulating contact with the femoral component, a tibia engaging member and a tibial tray engaged to the tibial bearing member and the tibia engaging member, the tibial tray comprising:

an upper plate having a portion configured for engaging the tibial bearing member;

a lower plate having a portion configured for engaging the tibia engaging member, said lower plate spaced apart from said upper plate and defining a plurality of cavities opening away from said upper plate, each of said cavities including a diaphragm adapted to flex when subjected to a load normal to the diaphragm;

a plurality of support posts, each connected between said upper plate and said diaphragm of a corresponding one of said plurality of cavities, wherein said support posts are circular in cross-section and have a diameter that is about 1/3 the diameter of the corresponding one of said plurality of cavities; and

a force sensing element disposed within each of said plurality of cavities and operable to produce an output signal in response to flexing of said diaphragm.

Claim 2. The tibial tray of claim 1, wherein said support posts each have a diameter of about 5.0 mm.

Claim 8. In a telemetric knee prosthesis adapted to measure forces transmitted across the knee joint, the knee prosthesis having a femoral component, a tibial bearing member in articulating contact with the femoral component, a tibia engaging member and a tibial tray engaged to the tibial bearing member and the tibia engaging member, the tibial tray comprising:

- an upper plate having a portion configured for engaging the tibial bearing member;

- a lower plate having a portion configured for engaging the tibia engaging member, said lower plate spaced apart from said upper plate and defining a plurality of cylindrical cavities opening away from said upper plate, each of said plurality of cylindrical cavities including a circular diaphragm adapted to flex when subjected to a load normal to the diaphragm and an outer wall;

- a plurality of support posts, each connected between said upper plate and said diaphragm of a corresponding one of said plurality of cylindrical cavities; and

- a force sensing element disposed within each of said plurality of cavities and operable to produce an output signal in response to flexing of said diaphragm, said force sensing element including four pairs of radially aligned strain gages, the strain gages of each pair arranged to measure differential strain in a radial direction and includes an inner gage mounted on said diaphragm adjacent the center of said circular diaphragm and an outer gage mounted on said diaphragm immediately adjacent said outer wall of said cylindrical cavity, wherein said circular diaphragm exhibits a micro-strain behavior under load that produces a maximum magnitude at a radial location from the center of said

circular diaphragm, and further wherein said inner gage is positioned to span said maximum magnitude radial location.

Claim 9. In a telemetric knee prosthesis adapted to measure forces transmitted across the knee joint, the knee prosthesis having a femoral component, a tibial bearing member in articulating contact with the femoral component, a tibia engaging member and a tibial tray engaged to the tibial bearing member and the tibia engaging member, the tibial tray comprising:

- an upper plate having a portion configured for engaging the tibial bearing member;

- a lower plate having a portion configured for engaging the tibia engaging member, said lower plate spaced apart from said upper plate and defining a plurality of cylindrical cavities opening away from said upper plate, each of said plurality of cylindrical cavities including a circular diaphragm adapted to flex when subjected to a load normal to the diaphragm and an outer wall;

- a plurality of support posts, each connected between said upper plate and said diaphragm of a corresponding one of said plurality of cylindrical cavities; and

- a force sensing element disposed within each of said plurality of cavities and operable to produce an output signal in response to flexing of said diaphragm, said force sensing element including four pairs of radially aligned strain gages, the strain gages of each pair arranged to measure differential strain in a radial direction and includes an inner gage mounted on said diaphragm adjacent the center of said circular diaphragm and an outer gage mounted on said diaphragm immediately adjacent said outer wall of said

cylindrical cavity, wherein said circular diaphragm exhibits a micro-strain behavior under load that produces a zero-crossing point between the center of said circular diaphragm and said outer wall of said cylindrical cavity, and further wherein said outer gage is positioned between said zero-crossing point and said outer wall.

Claim 10. The tibial tray of claim 9, wherein said circular diaphragm exhibits a micro-strain behavior under load that produces a negative maximum magnitude at a radial location between said zero-crossing point and said outer wall, and further wherein said outer gage is positioned to span said negative maximum magnitude radial location.

Claim 11. The tibial tray of claim 9, wherein said circular diaphragm further exhibits a micro-strain behavior under load that produces a positive maximum magnitude at a radial location from the center of said circular diaphragm, and further wherein said inner gage is positioned to span said positive maximum magnitude radial location.

Claim 12. In a telemetric knee prosthesis adapted to measure forces transmitted across the knee joint, the knee prosthesis having a femoral component, a tibial bearing member in articulating contact with the femoral component, a tibia engaging member and a tibial tray engaged to the tibial bearing member and the tibia engaging member, the tibial tray comprising:

an upper plate having a portion configured for engaging the tibial bearing member;

a lower plate having a portion configured for engaging the tibia engaging member, said lower plate spaced apart from said upper plate and defining a plurality of cavities opening away from said upper plate, each of said plurality of cavities including a diaphragm adapted to flex when subjected to a load normal to the diaphragm, said lower plate further defining a central cavity disposed between said plurality of cavities and a plurality of wiring channels, each communicating between a corresponding one of said plurality of cavities and said central cavity;

a plurality of support posts, each connected between said upper plate and said diaphragm of a corresponding one of said plurality of cavities;

a force sensing element disposed within each of said plurality of cavities and operable to produce an output signal in response to flexing of said diaphragm said force sensing element including four pairs of radially aligned strain gages, the strain gages of each pair arranged to measure differential strain in a radial direction;

a circuit element disposed in said central cavity for processing said output signal from said force sensing element in each of said plurality of cavities; and

wiring electrically connecting each force sensing element in said plurality of cavities to said circuit element to transmit said output signal, said wiring disposed in a corresponding one of said plurality of wiring channels,

wherein said lower plate defines a plane perpendicular to the sagittal plane of the knee joint when the knee prosthesis is implanted therein,

wherein each of said four pairs of strain gages is aligned in a one of two radial planes that are at about 45 degrees relative to said sagittal plane, and

wherein none of said four pairs of radially aligned strain gages is aligned with said wiring channel communicating with said corresponding one of said plurality of cavities.

Claim 13. The tibial tray of claim 12, wherein said four pairs of radially aligned strain gages are aligned at an angle of about 45 degrees or 135 degrees relative to said wiring channel.

Claim 14. A telemetric knee prosthesis comprising:

an upper tibial tray plate having a portion configured for coupling with a tibial bearing member;

a lower tibial tray plate spaced apart from the upper tibial tray plate and defining a plurality of cavities opening away from the upper tibial tray plate, each of the plurality of cavities including an outer wall and a diaphragm adapted to flex when subjected to a load on the diaphragm;

a plurality of support posts, each of the plurality of support posts extending between the upper tibial tray plate and the diaphragm of a corresponding one of the plurality of cavities; and

a plurality of force sensing elements, each of the plurality of force sensing elements disposed within one of the plurality of cavities and operable to produce an output signal in response to flexing of the diaphragm in the respective one of the plurality of cavities, each of the plurality of force sensing elements including an inner gage positioned such that at least a portion of the inner gauge is mounted at a location on one

side of the diaphragm directly opposite to where a portion of the corresponding one of the plurality of support posts contacts the other side of the diaphragm.

Claim 15. The tibial tray of claim 14, wherein at least a portion of the inner gauge is mounted on the one side of the diaphragm at a radius of less than about 2.5 mm from the center of the diaphragm.

Claim 16. The tibial tray of claim 14, wherein the diaphragm is a circular diaphragm which exhibits a micro-strain behavior under load that produces a maximum magnitude at a radial location from the center of the circular diaphragm, and further wherein the inner gage is positioned to span the maximum magnitude radial location.

Claim 17. The tibial tray of claim 16, wherein:

the circular diaphragm exhibits a micro-strain behavior under load that produces a zero-crossing point between the center of the circular diaphragm and the outer wall of the cylindrical cavity; and

each of the plurality of force sensing elements further comprises an outer gage positioned between the zero-crossing point and the outer wall.

Claim 18. The tibial tray of claim 14, wherein the support posts are circular in cross-section.

(9) EVIDENCE APPENDIX

None.

(10) RELATED PROCEEDINGS APPENDIX

None.